



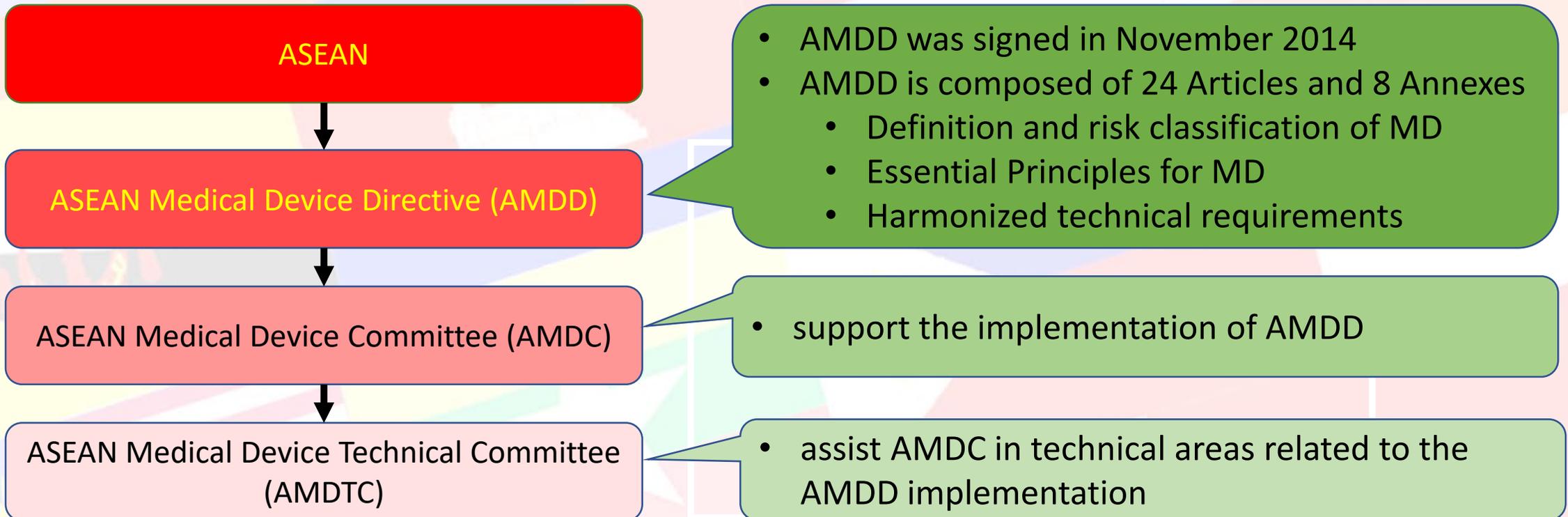
# AMDC Update

Mrs. Korrapat Trisarnsri  
Chair of the 8<sup>th</sup> AMDC

Director of Medical Device Control Division  
Thai Food and Drug Administration  
Ministry of Public Health, Thailand



# About AMDC





# The 8<sup>th</sup> Meeting of the ASEAN Medical Device Committee (AMDC) 4-8 August 2019 in Philippines

1

**Workshop on Post Market Surveillance by the US DoC**  
4<sup>th</sup>-5<sup>th</sup> August 2019

2

**5<sup>th</sup> ASEAN Medical Device Technical Committee (AMDTC)**  
6<sup>th</sup>-7<sup>th</sup> August 2019  
**Chair** : Indonesia  
**Vice-Chair** : Singapore

3

**8<sup>th</sup> ASEAN Medical Device Committee (AMDC)**  
7<sup>th</sup>-8<sup>th</sup> August 2019  
**Chair** : Thailand  
**Vice-Chair** : Vietnam



# 5<sup>th</sup> AMDTDC Meeting

## Risk Classification

- AMDTDC has reached consensus on the list of harmonized **66** medical device risk classification

- AMDTDC has agreed on the revised list of **82** borderline products

## Borderline Product



# Ratification of AMDD

**Myanmar**   
Completed June 2018

**Laos PDR**   
Completed March 2019

**Vietnam**   
Completed 2016

**Cambodia**   
Completed 22 March 2019

**Thailand**   
2020

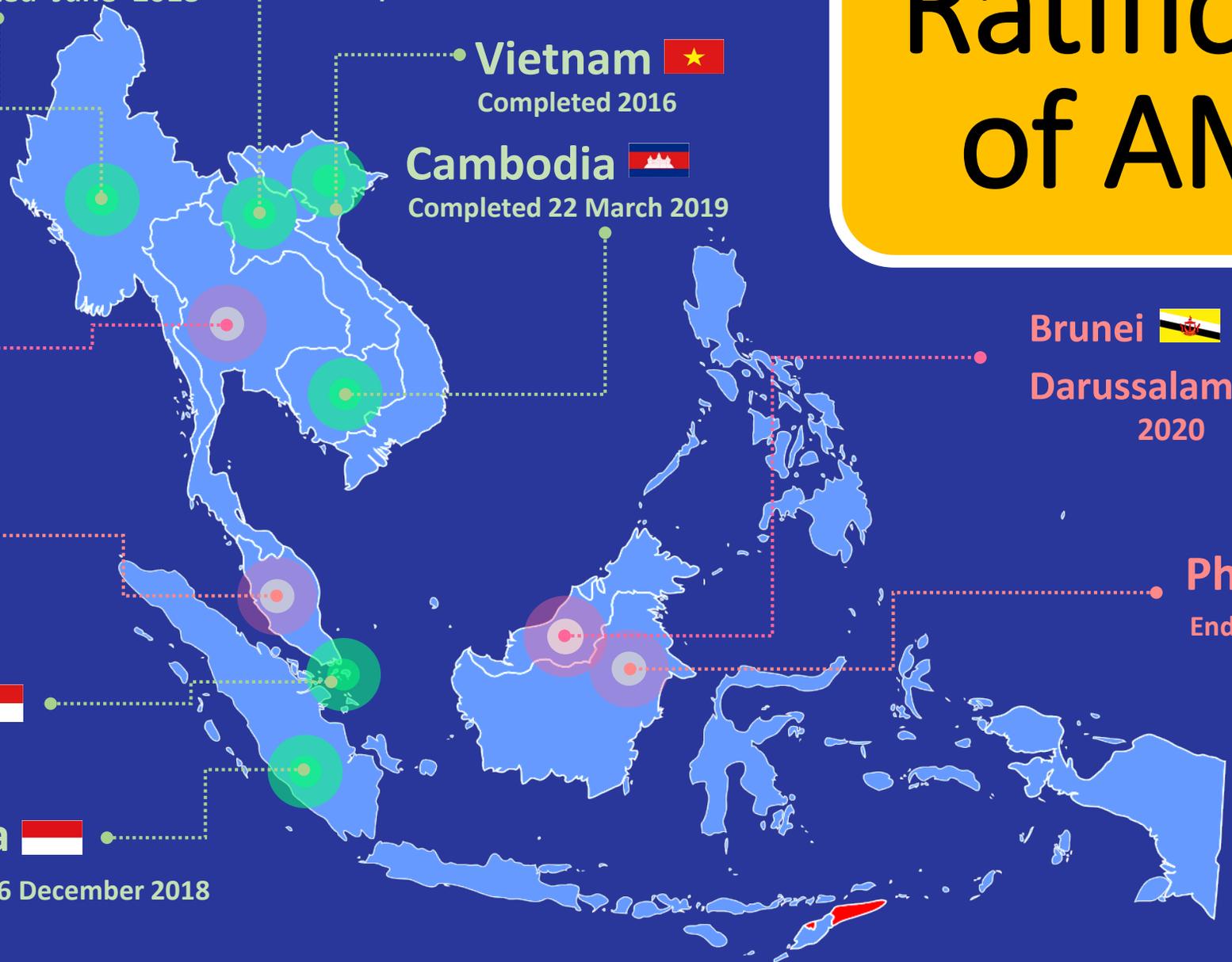
**Brunei Darussalam**   
2020

**Malaysia**   
the end of 2019

**Philippines**   
End of October 2019

**Singapore**   
10 November 2015

**Indonesia**   
Completed 26 December 2018





# Cooperation with other agencies

## US DoC

- before any future workshop, the US DoC to share the program of the workshop to AMS and give ample time to AMS to review it.

## PMDA

- through in-country workshop
- the topics for the new workshops as follow
  - Post Marketing System,
  - Premarket review of specific devices,
  - Third party certification program and
  - Quality Management System

## Korea

- Further discussed in the 2nd ACCSQ-Korea Dialogue which will be held back-to-back with the 52nd ACCSQ Meeting

Cooperation



The 9<sup>th</sup> AMDC Meeting is tentatively to be held at the week commencing 4 April 2020, Halong city, Viet Nam

**Thank you**